

Attorney Docket No.: **MGU-0020**
Inventors: **Polychronakos, Constantin**
Serial No.: **10/695,014**
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REMARKS

Claims 1-11 are pending in the instant application. Claims 1-10 have been rejected and claim 11 has been objected to. Claims 1, 10 and 11 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Claim Objections

Claims 1 and 11 have been objected to. It is suggested that the recitation of "unit for said" in claim 1 should be replaced with "unit for measuring". Further, it is suggested that " T_m " in claim 11 should be replaced with "a specific DNA sequence melting temperature T_m ". To clarify the device of the instant invention, Applicant has amended claim 1 to indicate that the device contains a measuring unit for obtaining an impedance measurement as supported by the teachings at page 6, lines 18-25; page 15, lines 18-24 and claim 1 as filed. Likewise, claim 11 has been appropriately amended. It is therefore respectfully requested that these objections be withdrawn.

II. Rejection of Claims Under 35 U.S.C. §112

Claims 1-9 have been rejected under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement. In particular, it is suggested that the specification fails to describe "a means for comparing said impedance measurement evoked current with a predetermined value to obtain a comparison" as recited in claim 1. It is acknowledged that the specification details using a measured impedance to determine glucose level and discusses impedance

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measurements at length, however, it is suggested that current is not addressed in a similar fashion. Moreover, the Examiner suggests that the specification lacks an explanation of the phrase "impedance measurement evoked current" and it is not clear whether an impedance measurement or a current measurement is meant by the phrase.

Page 6, lines 18-25 of the instant specification discloses the general principle behind the device and methods of the instant invention. This passage teaches that as progressively larger amounts of glucose bind to ConA, the electrochemical properties of the surface are altered, including the impedance. Such impedance measurements can be easily obtained, wherein a reproducible shift in the impedance curve of the semiconductor can be translated into levels of glucose based upon a calibration standard. Accordingly, in an earnest effort to clarify the instant invention, Applicant has amended the claims to impart these general principles. In light of these amendments, it is respectfully requested that this rejection be reconsidered and withdrawn.

III. Rejection of Claims Under 35 U.S.C. §102

Claims 1-3, 7 and 8 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,497,772 to Schulman et al. It is suggested that the '772 patent discloses a glucose quantification device comprising a reference electrode **REF1**, a counter electrode **CNTR**, and a working electrode **W1** with a semipermeable membrane **55**, **56**, **96**, and **100**. It is suggested that during use, these electrodes are immersed in a liquid medium in which at least one chemical entity is dissolved and a potentiostat **60**

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applies a measurement potential to the working electrode relative to the reference electrode corresponding to a measurement voltage during at least a portion of the measurement period, thereby causing the chemical entity to participate in an electrochemical reaction. The reaction is suggested to result in an impedance measurement evoked current, which is measured by a measuring unit **75** and a monitor compares the current with a predetermined value to obtain a comparison unit. The Examiner suggests that the liquid medium of the '772 patent is blood as set forth in claim 2 of the instant invention; the chemical entity of the '772 patent is glucose as set forth in claim 3 of the instant invention; the reference electrode of the '772 patent is silver chloride as set forth in claim 7 of the instant invention; and the counter electrode of the '772 patent is platinum as set forth in claim 8 of the instant invention. Applicant respectfully traverses this rejection.

The '772 patent teaches an electrochemical oxygen detector made up of electrodes. By using glucose oxidase, which converts glucose and oxygen to gluconate and hydrogen peroxide, the amount of oxygen in the blood is directly proportional to the amount of glucose in the blood. The amount of oxygen in the blood is determined as a function of the amount of current flowing through the working electrode. Thus, while this reference teaches a unit for measuring current, this reference is silent to a device comprising a measuring unit for obtaining impedance measurements. Current and impedance are fundamentally different measurements; impedance is the resistance of a component at a given frequency, whereas current is the amount of electric charge flowing past a specified circuit point per unit time. As the

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'772 patent fails to teach each and every element of the claims as set forth by MPEP 2131, this reference does not anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

IV. Rejection of Claims Under 35 U.S.C. §103

Claims 1-5, 7, and 9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2004/0011671 to Shults in view of U.S. Patent No. 6,207,369 to Wohlstadter et al. It is suggested that the Shults discloses a glucose quantification device comprising a reference electrode **20**, a counter electrode **22**, and a working electrode **21** with a semipermeable membrane, wherein the sensor is immersed in a liquid medium in which at least one chemical entity is dissolved. It is further suggested that the electron circuit means used with this sensor can be that of U.S. Patent No. 5,497,772 as discussed *supra*. The Examiner suggests that while Shults teaches a working electrode comprising platinum rather than a semiconductor, Wohlstadter describes a sensor having a working electrode comprising platinum or a semiconductor, which are functionally equivalent in a glucose sensor.

Claims 9 and 10 are also rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,569,186 to Lord et al. in view of Schulman. It is suggested that Lord et al. disclose a method and system in which signals from an implantable glucose sensor **20** are used to control administration of insulin to modulate a patient's glucose levels via a feedback loop pump **10**. The Examiner suggests that while Lord et al. generally disclose a glucose sensor comprising an implantable enzyme electrode, Schulman

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provides the details of the glucose sensor as discussed *supra*. It is suggested that it would have been obvious to use the sensor of Schulman with the system of Lord et al., since Lord et al. teach using an implantable glucose sensor and Schulman describes such a sensor. Applicant respectfully traverses these rejections.

The glucose sensor of Schulman is used as a basis for the instant rejection of claims 1-5, 7, 9, and 10; however, as indicated *supra*, Schulman does not teach or suggest a device comprising a measuring unit for obtaining impedance measurements. As Shults, Wohlstadter et al., and Lord et al. are also silent to impedance measurements, these references fail to compensate for the deficiencies of the teachings of Schulman. MPEP 2143 indicates that the combined references must teach or suggest all the claim limitations. As the cited references fail to meet this requirement, they fail to make the instant invention obvious. It is therefore respectfully requested that this rejection be withdrawn.

V. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

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Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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Date: **March 14, 2005**

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